UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 6, 2018

Mr. W. Lee Cox, Chief
Radiation Protection Section
Division of Health Service Regulation
5505 Creedmoor Road, 1st Floor
Raleigh, NC 27612

Dear Mr. Cox:

On June 7, 2018, the Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States Liaison to the MRB, met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the North Carolina Agreement State Program. The MRB found the North Carolina Agreement State program adequate to protect public health and safety and compatible with the NRC's program.

The enclosed final report contains a summary of the IMPEP team's findings (Section 5.0) and recommendations. The review team made one recommendation regarding the performance of the North Carolina Agreement State Program during this review. Based on the results of the current IMPEP review, the next full IMPEP review will take place in approximately 4 years, with a periodic meeting in approximately 18 months.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Scott W. Moore, Deputy Director
Office of Nuclear Material Safety
and Safeguards

Enclosure:
North Carolina Final IMPEP Report

cc: Jay Hyland, ME
Organization of Agreement States
Liaison to the MRB

SUBJECT: NORTH CAROLINA FY2018 FINAL IMPEP REPORT

Date: July 6, 2018

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NORTH CAROLINA AGREEMENT STATE PROGRAM

March 5–9, 2018

FINAL REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the North Carolina Agreement State Program. The review was conducted during the period of March 5–9, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Kansas.

Based on the results of this review, the team recommended, and the Management Review Board (MRB) agreed, that North Carolina's performance was satisfactory for all applicable indicators, except for the non-common performance indicator, Sealed Source and Device (SS&D) Evaluation Program, which was found satisfactory, but needs improvement.

The MRB supported the team's sole recommendation (see Section 5.0) and agreed that the recommendations from the 2014 IMPEP review should be closed (see Section 2.0).

Accordingly, the team recommended, and the MRB agreed, that the North Carolina Agreement State Program is adequate to protect public health and safety and compatible with the NRC's program. When weaknesses in a program result in, or could result in, less than fully satisfactory performance for one or more performance indicators, the NRC's Management Directive 5.6, "Integrated Performance Evaluation Program (IMPEP)," states that the MRB should consider whether Monitoring by the NRC is warranted. The team discussed whether or not Monitoring was appropriate based on the satisfactory, but needs improvement, finding for the indicator SS&D Evaluation Program. Based on North Carolina's willingness and promptness to correct the deficiencies in its SS&D Evaluation Program, the mitigating circumstances related to the deficiencies, and the low volume of evaluations completed by the staff each year, the team stated that North Carolina did not warrant Monitoring. Instead, the team recommended that a periodic meeting take place in approximately one year with the intent to conduct the next IMPEP review in 4 years. The MRB agreed that Monitoring was not necessary, but directed that a periodic meeting take place approximately 18 months following the 2018 IMPEP review. The MRB directed that the meeting should include an extended discussion on North Carolina's SS&D evaluation program. The timing of the periodic meeting should provide North Carolina sufficient time to take actions to address the deficiencies noted in Section 4.2. Depending upon the progress noted at the time of the periodic meeting, the MRB may choose to direct a period of Monitoring, a followup review, a second periodic meeting, or alter the timing of the next full IMPEP review.

1.0 INTRODUCTION

This report presents the results of the review of the North Carolina Agreement State Program radioactive materials safety program. The review was conducted during the period of March 5–9, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Kansas. Team members are identified in Appendix A. The review was conducted in accordance with the "Agreement State Program Policy Statement," published in the *Federal Register* on October 18, 2017, and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of March 8, 2014, to March 9, 2018, were discussed with North Carolina management on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and applicable non-common performance indicators was sent to North Carolina on January 2, 2018. North Carolina provided its response to the questionnaire on February 23, 2018. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML18057A054.

A draft of this report was issued to North Carolina on April 4, 2018, for factual comment (ADAMS Accession Number ML18093B541). North Carolina responded to the findings and conclusions of the review by letter dated May 1, 2018. A copy of this response is available in ADAMS (Accession Number ML18134A346). The Management Review Board (MRB) convened on June 7, 2018, to discuss the team's findings.

The North Carolina Agreement State Program is administered by the Radiation Protection Section (the Section) within the Division of Health Service Regulation (the Division). The Division is part of the Department of Health and Human Services (the Department). Within the Section, the Radioactive Materials Branch (the Branch) administers the radioactive materials program and performs the responsibilities of the Agreement State Program. Organization charts for North Carolina are available in ADAMS (Accession Number ML18057A042).

At the time of the review, the North Carolina Agreement State Program regulated 569 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of North Carolina.

The team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicators and made a preliminary assessment of the North Carolina Agreement State Program's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on March 7, 2014. The final report is available in ADAMS (Accession Number ML14167A295). The results of the review and the status of the recommendations are as follows:

Technical Staffing and Training: Satisfactory, but Needs Improvement

Recommendation 1: The review team recommends that North Carolina update its training qualification program to be consistent with NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualification Program for Federal and State Material and Environmental Management Programs" and the State apply this program to all technical staff currently going through the qualification process and all new staff that are hired.

Status: In July 2015, the Branch revised its training and qualification program to make it consistent with IMC 1248. The revised program is utilized by all staff, including staff currently progressing through the qualification process, and will be applied to new staff hired by the Branch. The Branch Manager now meets monthly with staff currently completing the qualification program to review progress and ensure staff is receiving the training, both formal and on the job, as needed. The Branch Manager also tracks all refresher training for qualified staff. Additionally, the Branch has implemented a more restrictive requirement of 40 hours of refresher training every 2 years for qualified staff.

This recommendation is closed.

Status of Materials Inspection Program: Satisfactory

Recommendation 2: The review team recommends that North Carolina implement procedures and a new tracking system to ensure that less than 10 percent of Priority 1, 2, and 3 and initial inspections are completed overdue.

Status: The 2014 IMPEP review found that the Branch performed 9 percent of its inspections overdue during the review period. This was primarily due to 30 percent (21 of 71) of initial inspections being conducted overdue. The 2014 team determined that the initial inspections were conducted late due to database entry errors and improper tracking. However, the IMPEP report noted that the Branch's database issues extended beyond the missed initial inspections. Prior to the 2014 onsite review, North Carolina found approximately 200 data entry errors in the inspection database.

Since the 2014 IMPEP review, the Branch has actively worked to ensure that database errors do not cause inspections to be performed overdue. The Branch uses the distributed version of the NRC's web based licensing (WBL) system. The Branch has established new queries and reports in WBL so that management can adequately track upcoming inspections. These reports provide information regarding new licenses issued, as well as initial and routine inspection due dates. Additionally, the Branch has established several inspection frequencies that are more restrictive than the NRC's. Increasing the inspection frequency gives the Branch a greater window to conduct inspections consistent with the criteria in IMC 2800, "Materials Inspection Program." Lastly, the Branch established a new role to facilitate quality assurance and control reviews of inspection reports. This role was assigned to a senior staff member who is responsible for ensuring that the next inspection due date is captured accurately in WBL by the inspector after completing an inspection. All of these

actions taken by the Branch contributed to it performing only 3.8 percent of Priority 1, 2, 3, and initial inspections overdue during the current review period.

This recommendation is closed.

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory
Recommendation: None

Technical Quality of Incident and Allegation Activities: Satisfactory
Recommendation: None

Compatibility Requirements: Satisfactory
Recommendation: None

Sealed Source and Device (SS&D) Evaluation Program: Satisfactory, but Needs Improvement

Recommendation 3: The review team recommends that North Carolina identify, develop and implement processes to ensure official sealed source and device registry documents are complete, legible, accounted for, and are readily accessible to those who are determined to have a need to know the information.

Status: The Branch developed and implemented a procedure that provides staff members with instruction on how to review SS&D applications and issue certificates. The procedure established roles and responsibilities for Branch staff and provided instruction on how to receive and upload electronic copies of application material to WBL and to a shared drive. This procedure was implemented in February 2018. Therefore, the team could not effectively evaluate the Branch's implementation of the procedure during this review.

Because the Branch responded to this recommendation, this recommendation is closed. However, due to the continued weaknesses in North Carolina's SS&D program, a new recommendation involving this indicator was opened.

The new recommendation includes elements of the 2014 recommendation on North Carolina's SS&D program (see Section 4.2).

Overall finding: Adequate to protect public health and safety, but needs improvement, and compatible with the NRC's Program.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training; (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

a. Scope

The team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated North Carolina's performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is equivalent to IMC 1248.
- Qualification criteria for new technical staff are established and are followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

The Branch is comprised of 14.5 full time equivalents (FTE) which includes: a manager, three team leads (for licensing, security and response, and inspections), an administrative assistant that coordinates reciprocity activities and uploads license actions, an environmental consultant that serves as both quality assurance reviewer and rule writer, three license reviewers, three inspectors, a hybrid inspector and license reviewer, an environmental program coordinator, and a general license coordinator. All staff, except the administrative assistant and manager, are classified as health physicists. There were no vacancies at the time of the review.

While evaluating this indicator, the team considered the number of staff who have left the Branch over the review period and how those losses could potentially impact the Branch's performance. Over the review period, three staff left the program for various reasons and seven staff were hired, including the Branch Manager. One staff member left the Branch in 2014 to pursue an additional degree and two departed in 2016; one retired and the other left to seek other opportunities. New staff were hired within 5 to 7 months in each case; however, because the Branch increased FTE during the review period, the loss of staff had minimal impact. The team determined that the Branch has sufficient staff to carry out the responsibilities of the Agreement State Program and a good balance between licensing and inspection staffing levels.

As mentioned in North Carolina's response to the questionnaire, the Branch was in the process of reorganizing. This reorganization is meant to increase efficiency in the management of the Branch and provide advancement opportunity for staff by creating inspection and licensing lead positions. The reorganization was completed shortly after the onsite review.

As noted in Section 2.0, North Carolina has implemented a qualification and training program that is consistent with the NRC's IMC 1248. The training program is managed by the Branch Manager who meets regularly, with staff undergoing qualification and guides them through the training process. The Branch Manager also determines when staff members are sufficiently trained to work independently, including partial qualification for certain activities.

Since implementing the new training and qualification program, Branch staff are cognizant of training requirements and are qualified in an appropriate amount of time. At the time of the review, there were three staff in different stages of qualification, as well as one staff member who achieved full licensing qualification just prior to the review. Several staff are receiving training and experience to meet the qualification criteria to perform both licensing and inspection in certain cases. Staff spoke highly of the Branch Manager's commitment to training, as well as the Branch's use of team inspections, and peer and mentor review of licensing and inspection activities.

c. Evaluation

The team determined that, during the review period, North Carolina met the performance indicator objectives listed in Section 3.1.a., and, based on the criteria in MD 5.6, recommended that North Carolina's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found North Carolina's performance with respect to this indicator to be satisfactory.

3.2 Status of Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in the NRC's IMC 2800 and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated North Carolina's performance with respect to the following performance indicator objectives:

- Initial inspections and inspections of Priority 1, 2, and 3 licensees are performed at the frequency prescribed in IMC 2800.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, "Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."
- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections; or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports").

b. Discussion

The Branch performed 505 Priority 1, 2, 3, and initial inspections during the review period. Of those inspections, 10 Priority 1, 2, and 3 and 8 initial inspections were conducted overdue for a total of 3.8 percent of Priority 1, 2, 3, and initial inspections completed overdue during the review period. Section 2.0 discusses some of the steps the Branch took to ensure inspections were conducted on time following the 2014 IMPEP review. The Branch's inspection frequencies are the same as, and in some instances more frequent than, the NRC's inspection frequencies for similar license types in IMC 2800.

A sampling of 25 inspection reports indicated that three inspection results were communicated to licensees beyond the Branch's goal of 30 days after the inspection exit. The three findings issued beyond 30 days occurred early in the review period. During the review period, the Branch updated its procedures and added time frames to its administrative processes to ensure inspection results are issued in a timely manner. All inspection results were issued within 30 days of the inspection exit for the sampled inspection reports that occurred in the second half of the review period.

The team evaluated the Branch's performance of reciprocity inspections throughout the review period. The team determined that during each year of the review period, the Branch performed greater than 20 percent of candidate reciprocity inspections.

c. Evaluation

The team determined that, during the review period, North Carolina met the performance indicator objectives listed in Section 3.2.a., and, based on the criteria in MD 5.6, recommended that North Carolina's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found North Carolina's performance with respect to this indicator to be satisfactory.

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide assurance that licensee activities are carried out in a safe and secure manner. Accompaniments of inspectors performing inspections, and the critical evaluation of inspection records, are used to assess the technical quality of an Agreement State's inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated North Carolina's performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, procedures are established and followed to provide feedback information to license reviewers.
- Inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors involved in 30 materials inspections conducted during the review period, including security inspections which, in North Carolina, are conducted separately from routine inspections. The casework reviewed included inspections conducted by eight of the Branch's inspectors and covered industrial radiography, academic, broad scopes, medical with and without written directives, panoramic irradiators, security, portable gauges, brachytherapy, pharmacies, and high dose rate remote afterloaders. Additionally, a team member accompanied four program inspectors the week of January 22, 2018. The inspector accompaniments are identified in Appendix B.

The accompanied inspections were thorough and of high quality. Inspectors consistently displayed both technical expertise and courteousness toward licensees. One of the inspections uncovered several non-compliances which were handled in an effective manner.

Inspection reports contain a significant amount of information. Additional inspection-related notes concerning correspondence to licensees, as well as how and when the licensee responds to the correspondence, are kept in WBL along with the inspection history. At the time of the review, the Branch was in transition from a

locally-hosted WBL to an NRC-hosted version and the NRC-hosted version had been recently implemented. The team noted that, at the time of the review, Branch staff continued to take notes using the old form to document and track information in addition to the new WBL notes form.

When an inspection reveals non-compliance issues, the next inspector copies the non-compliances into a new checklist for use during their inspection. This checklist is used in the preparation of and in the documentation of each new inspection. In the case files reviewed, the section on previous non-compliances was given more than a perfunctory write-up. The Branch documents inspections so that routine inspection reports are separate from field and security inspections.

When a licensee receives a non-compliance notice, it is required to respond in a timely manner. Licensee responses are required to identify root causes for each non-compliance. One inspection evaluated as part of this review resulted in the correction of items in a license.

The Branch Manager, or in some cases, the lead inspector, accompanies each inspector once per year. Summaries of these accompaniments are created to reflect on what improvements can be made. Based on the team's review of the summaries, previously noted inspection issues have been improving in subsequent years. For example, reminders and pointers from the 2015 summary were noted as good practices by inspectors in the 2017 summary. Both the Branch Manager and lead inspector are long-tenured inspectors and/or supervisors. Uniquely, all inspections are reviewed by a single designated reviewer who is neither management nor the lead inspector. That reviewer provides a summary of non-compliance issues to the entire inspection group approximately eight times per year.

c. Evaluation

The team determined that, during the review period, North Carolina met the performance indicator objectives listed in Section 3.3.a., and, based on the criteria in MD 5.6, recommended that North Carolina's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found North Carolina's performance with respect to this indicator to be satisfactory.

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the North Carolina licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated North Carolina's performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements are consistent with current regulatory guidance (e.g., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk-significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, North Carolina performed 2,265 radioactive materials licensing actions. The team evaluated 22 of these actions. The licensing actions selected for review included two new applications, seven amendments, eight renewals, two terminations, two decommissioning/terminations, and one decommissioning/site closure. The team evaluated casework which included the following license types and actions: broad scope medical; diagnostic nuclear medicine; commercial manufacturing only; commercial distribution — nuclear pharmacies; industrial radiography; research and development; education — broad scope; nuclear pharmacy; gauges; industrial lab; outpatient radiopharmaceutical therapy — radium; brachytherapy only; service and/or repair (including relocation); gamma knife (hospital based); Group I-IV medical cyclotron; decommissioning actions; and financial assurance. The casework sample represented work from five license reviewers including the team leader of licensing.

At the end of 2014, all of North Carolina's licensing documents were made electronically available. In 2015, the Branch began issuing renewal licenses for 10 years if the eligibility criteria stated in the materials license cover letter were met. If the eligibility criteria is not met, the renewal license will be issued for five years. As of March 1, 2016, the Branch had its licensees, who were under the Increased Controls and Fingerprinting Orders, begin implementation of 10 CFR Part 37. The Branch updated its licensing procedures in March 2018 and plans to begin using the NRC-hosted version of WBL on April 1, 2018.

The team found that licensing actions were thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed. The licensing cases reviewed demonstrated that, with isolated exceptions, proper guidance was followed, and deficiency letters and license conditions were well supported by information contained in the licensing files. Terminated licensing actions were well documented, showing appropriate transfer and final status surveys, as appropriate.

c. Evaluation

The team determined that, during the review period, North Carolina met the performance indicator objectives listed in Section 3.4.a., and, based on the criteria in MD 5.6, recommended that North Carolina's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found North Carolina's performance with respect to this indicator to be satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and followup actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated North Carolina's performance with respect to the following performance indicator objectives:

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety, or security significance.
- Appropriate followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED).
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 141 incidents involving radioactive materials were reported to the Branch. The team evaluated 10 reportable and 4 non-reportable radioactive materials incidents which included 2 lost/stolen radioactive materials, 6 medical events, 3 damaged equipment, 2 motor vehicle accidents, and 1 contaminated material event. The Branch dispatched inspectors for onsite followup for all of the cases reviewed.

The Branch has procedures in place for the evaluation and follow-up of incidents and allegations. The team determined that the procedures were compatible with equivalent NRC procedures. When the Branch receives an incident or allegation, the Response Coordinator is responsible for its initial evaluation, the determination of whether or not an on-site investigation is required, assigning inspectors to investigate and determining the priority for that inspection, and reporting the event to the NRC, as required.

The team determined that initial responses were prompt and well-coordinated and the level of effort was commensurate with the health and safety significance of the event. For all events reviewed, the Branch notified the NRC's Headquarters Operations Center and entered and/or updated the information in NMED in a timely manner.

During the review period, 16 allegations were received by the Branch. The team evaluated four allegations, including one allegation that the NRC referred to North Carolina, during the review period. The team determined that the Branch's follow-up to the allegations was appropriate and that the Branch provided responses to concerned individuals when contact information was provided. Additionally, the team determined that the Branch can and does protect the concerned individual's identity to the extent practicable.

c. Evaluation

The team determined that, during the review period, North Carolina met the performance indicator objectives listed in Section 3.5.a., and, based on the criteria in MD 5.6, recommended that North Carolina's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found North Carolina's performance with respect to this indicator to be satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements; (2) SS&D Evaluation Program; (3) Low-Level Radioactive Waste Disposal (LLRW) Program; and (4) Uranium Recovery Program. The NRC's Agreement with North Carolina retains regulatory authority for a uranium recovery program; therefore, only the first three non-common performance indicators applied to this review.

4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than three years after the effective date of the NRC's final rule. Other program elements, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as necessary for maintenance of an adequate and compatible program, should be adopted and implemented by an Agreement State within 6 months following NRC designation.

a. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated North Carolina's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC Web site at the following address: https://scp.nrc.gov/regtoolbox.html.

- The Agreement State Program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.
- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program, have been adopted and implemented within 6 months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Impact of sunset requirements, if any, on the State's regulations.

b. Discussion

North Carolina became an Agreement State on August 1, 1964. The current effective statutory authority is contained in Chapter 104E of the North Carolina General Statutes. In Section 104E-6, the Department is designated as the State's radiation control agency. The Branch implements the radiation control program.

The North Carolina regulations governing radiation protection requirements are located in North Carolina Administrative Code, Title 10A, Chapter 15, “Regulations for Protection against Radiation,” and apply to all ionizing radiation. North Carolina requires a license for possession and use of all radioactive material. The State has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

Rulemaking begins with the Branch recommending to the North Carolina Radiation Protection Commission (RPC) that rules are due for revision. The RPC then directs the Radioactive Materials Control Advisory Committee to commence rule development. Depending upon the complexity of the task, it can take 1 to 3 years to bring a set of rules to the RPC to be adopted.

In North Carolina’s rulemaking process, the Department must approve the rule and the Office of State Budget must approve an associated Fiscal Impact Statement (FIS). After the Department has approved of the rule and the FIS is approved, the RPC will vote to approve the rules for adoption. After the rule is approved for adoption by the RPC, it is published for public comment and a public hearing is held. Public comments are addressed and rule revisions are made, as necessary. If substantive changes are made, a second public comment period and public hearing is held. Once public comments are resolved, the RPC votes to submit rules for the Office of Administrative Hearings Rules Review Committee to review the final rule. The process concludes with the Rules Review Committee holding a hearing to review the rule. If the Rules Review Committee decides to accept the regulation, it becomes effective on the first day of the following month.

North Carolina requires a review of all regulations promulgated by the State every 10 years. Regulations that are not reviewed and approved prior to the end of the review period automatically expire. The Branch will need to review all radiation protection rules in 2018 and then report to the Rules Review Committee as to whether the rules are necessary and what, if any, public impact the rules have. The Branch anticipates this review of regulations as an opportunity to improve upon the consistency of and streamline its regulations.

During the review period, the Branch submitted 5 proposed regulation amendments and 14 final regulation amendments, including 3 revised final regulation amendments, to the NRC for a compatibility review. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than 3 years after they become effective. No regulations were late at the time of submission. At the time of the review, there were no amendments overdue for adoption with one exception. The Radioactive Materials Control Advisory Committee decided to not adopt an amendment to 10A NCAC 15.0117, which primarily contains items, such as definitions, that shifted from a different compatibility category to compatibility category NRC:

> These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations. These program elements are designated “NRC” and should not be adopted by Agreement States.

Potential incompatibilities created by not adopting the amended regulations were minimal. Additionally, Branch staff was aware of this issue while adopting other regulations and took steps to address portions of the amended rule. Branch staff plans to address this issue fully during the upcoming review of all regulations.

c. Evaluation

The team determined that, during the review period, North Carolina met the performance indicator objectives listed in Section 4.1.a., and, based on the criteria in MD 5.6, recommended that North Carolina's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found North Carolina's performance with respect to this indicator to be satisfactory.

4.2 Sealed Source and Device Evaluation Program

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides information on conducting SS&D reviews and establishes useful guidance for teams. Under this guidance, three sub elements: Technical Staffing and Training, Technical Quality of the Product Evaluation Program, and Evaluation of Defects and Incidents Regarding SS&D's, are evaluated to determine if the SS&D program is satisfactory. Agreement States with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

a. Scope

The team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated North Carolina's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Qualification criteria for new technical staff are established and are being followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- Management is committed to training and staff qualification.
- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D reviewers are trained and qualified in a reasonable period of time.

Technical Quality of the Product Evaluation Program

- SS&D evaluations are adequate, accurate, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3.

Evaluation of Defects and Incidents

- SS&D incidents are reviewed to identify possible manufacturing defects and the root causes of these incidents.
- Incidents are evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications to the NRC, Agreement States, and others, as appropriate, occur in a timely manner.

b. Discussion

Technical Staffing and Training

At the time of the review, the Branch had three staff that performed SS&D reviews and there were no vacancies in North Carolina's SS&D program. During the review period, one SS&D staff member left the program and one staff member was hired.

The Branch Manager keeps an electronic qualification journal for each staff member. The training program for SS&D reviewers, which is part of the Branch's overall Qualification and Training Manual, is equivalent to NRC training requirements listed in IMC 1248, Appendix D, with the exception of establishing the minimum number of completed evaluations a reviewer must complete to have signature authority for SS&D reviews. The Branch Manager noted that the number of evaluations to achieve signature authority was not established, so each SS&D reviewer's qualification could be tailored to the specific reviewer-in-training. The Branch Manager stated that North Carolina's qualification process requires that the reviewer perform two concurrence reviews on in-house evaluations to achieve limited qualification sign off authority for certain device reviews.

During the review period, one staff member received their SS&D qualification. The team identified that while the staff member was in training, the individual completed the qualification journal, which included individual study activities, specialized NRC courses, and on-the-job training. The staff member performed casework reviews of two amendment actions in-house, as well as a mock review of an historical SS&D case. The team also identified that the reviewer performed concurrence reviews and signed two SS&D evaluations before he had proper training and qualifications. Although the staff member had completed the SS&D qualification journal, given the types of SS&D manufacturers in North Carolina and the types of devices SS&D reviewers would be likely to review, the team discussed with the Branch Manager whether this level of experience was sufficient to gain full SS&D qualification and signature authority. The team noted that additional experience could be accomplished via mock reviews of historical cases or via reviews of in-house applications.

Qualified staff members are required to fulfill 40 hours of refresher training every 2 years. This requirement is greater than the NRC's expectation of 24 hours of refresher training every 2 years. For this review period, the two experienced reviewers and the single review-in-training all attended the NRC SS&D Workshop in 2017.

Technical Quality of the Product Evaluation

The Branch has 13 SS&D licensees and completed 7 SS&D evaluations during the review period. The team evaluated all seven of these SS&D evaluations. The reviews concerned one generally licensed device and two medical sources from two manufacturers in North Carolina. The evaluations included two applications for new products, four amendments, and one correction. No inactivations were issued by the Branch during the review period. At the time of the review, the Branch had no open SS&D evaluations and did not have a backlog.

As discussed in Section 2.0, the team noted that the Branch developed and implemented a procedure to ensure that SS&D documentation is complete and readily available to those with a need-to-know. However, this procedure was implemented in February 2018. Therefore, the team could not effectively evaluate the Branch's implementation of the procedure during this review.

The team noted that SS&D reviewers used NUREG-1556, Vol. 3, Rev. 2, as well as internal guidance, when completing SS&D reviews; however, implementation, and thus performance, was inconsistent. For example, the team identified that three of the seven SS&D evaluations did not fully address health and safety concerns and product integrity. The team identified that SS&D reviewers did not address the following issues in the evaluation of a new generally licensed device: (1) a leak test request that exceeded the typical 6 month frequency; (2) incomplete descriptions of the product design, construction of the product, and on/off indicators, including engineering drawings, (3) incomplete prototype testing documentation; (4) labeling that did not meet the North Carolina regulatory requirements for labeling of generally licensed devices; (5) no discussion of dose limits for generally licensed devices; and (6) incomplete radiation level information for one of the sources involved. In the subsequent amendment for this device, the following items were noted by the team: (1) the labeling was not corrected to meet generally licensed device regulatory requirements; (2) no documentation was found to justify adding models to a series, as discussed in NUREG-1556, Vol. 3, Rev. 2; and (3) the licensee did not submit information regarding changes to the product to accommodate new sources and a new source array. The issues detailed above were not identified during either the primary or the concurrence review for both evaluations.

During discussions with the team, the SS&D reviewers noted that they had observed the prototype testing of the device and that their familiarity with the device led them to forego some of the review items identified above. For example, during prototype testing, the device was tested under likely accident conditions and passed all tests. Additionally, the manufacturer submitted radiation level information for the open shutter condition. Since the device had passed all the likely accident conditions and the open shutter is the worst case scenario, the SS&D reviewers made the decision not to request the radiation level information for the closed shutter condition. The guidance in NUREG-1556, Vol. 3, Rev. 2, states that applicants should provide radiation levels when the device is in both the open and closed conditions. The reviewers also evaluated the possible doses based on the radiation level information and found them acceptable, but did not document the doses and did not ask the manufacturer to provide additional information. During the onsite review, the Branch drafted a letter to issue to the licensee requesting the missing information and corrections to the device labeling. While the guidance in NUREG-1556, Vol. 3, Rev. 2 was not followed for normal conditions of use and for the closed shutter

condition, the team recognizes that the SS&D reviewers assessed the most likely accident conditions and worst case dose scenarios. Therefore, the team did not identify significant health and safety concerns, despite the issues stated above.

The team identified that incorrect and incomplete labeling was a recurring issue in all seven SS&D registrations. In the evaluation of a new medical source, the team found that the Branch did not address health and safety issues related to prototype testing, conditions of normal use and likely accident conditions. Both SS&D reviewers involved noted the inconsistency of the applicant's prototype testing results with the appropriate American National Standards Institute (ANSI) standard, but failed to address the inconsistency with the applicant. Additionally, SS&D reviewers did not request justification for accepting a lower ANSI classification obtained after testing of the product. The labeling for this medical source and another medical source from the same manufacturer evaluated during the review period was also inconsistent with the Branch's, as well as the NRC's labeling requirements.

For this particular medical device, the Branch conducted a safety evaluation on a similar device during the previous IMPEP review period. The technology for both devices is essentially the same; therefore, certain aspects of the device, such as the conditions of normal use and likely accident conditions, had already been reviewed by the Branch. Thus, the SS&D reviewers did not request this information for the new device. The prototype testing of this device was identical to the one conducted for the manufacturer's other medical device and therefore was deemed acceptable by the SS&D reviewers.

The team noted that reference documents and deficiency letters were missing from six of the seven evaluations that the team reviewed. The team identified that the procedures implemented by the Branch do not encourage the use of memos to file for reviewers to document administrative amendments where safety evaluations are not necessary or to document a reviewer's decision-making process. During the onsite review, the lead SS&D reviewer located the missing reference documents and deficiency letters and added them to the corresponding folders in the Branch's shared drive.

Based on the issues identified above, the team recommended that North Carolina take action to: (1) improve the thoroughness, completeness, accuracy, and consistency of SS&D reviews and ensure that the reviews address health and safety concerns and product integrity; (2) improve the concurrence review process to ensure that concurrence reviewers fully assess SS&D evaluations; and (3) ensure that each SS&D evaluation is properly documented, including all licensee correspondence, deficiency letters and responses, and memos to file.

Evaluation of Defects and Incidents Regarding SS&Ds

There were no incidents involving a SS&D registered product reported to the Department during the review period.

Evaluation of Defects and Incidents Regarding SS&Ds

There were no incidents involving a SS&D registered product reported to the Department during the review period.

c. Evaluation

The team determined that, except as noted below, during the review period North Carolina met the performance indicator objectives listed in Section 4.2.a.

- Individuals performing SS&D evaluation activities are not always adequately qualified and trained to perform their duties.
- SS&D evaluations are not always adequate, accurate, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3.

The team discussed with the Branch Manager whether the cases reviewed by the reviewer-in-training were commensurate to the types of devices manufactured or distributed in North Carolina, as well as whether this level of training was sufficient to justify full signature authority.

Although the team believes that all of the devices reviewed are safe, the team noted that three of the seven SS&D evaluations did not fully address health and safety concerns and indicated repeated examples of issues with respect to thoroughness, completeness, consistency, clarity, technical quality, adherence to existing guidance in product evaluations, and addressing the integrity of the product. The team noted that in some instances, the SS&D reviewers had considered and evaluated some of the issues identified by the review team during the onsite review. However, the SS&D reviewers did not document their communications with the licensee, internal discussions during the evaluation of the device, and/or evaluation decisions. Due to the inconsistent quality of the reviews performed during the review period, specifically for new products, the team has concerns that without improvement to the SS&D evaluation program, the Branch may fail to identify issues which could impact health and safety.

The team noted that all seven evaluations completed during the review period were processed before the Branch implemented procedures to ensure the completeness of SS&D documentation. Therefore, although the team believes that adherence to these procedures should strengthen the Branch's SS&D evaluations, not enough time has passed for the team to evaluate the effectiveness of their procedures.

During the onsite review, the Branch took steps to correct some of the issues mentioned above, including drafting correspondence to request more information from a licensee and corrections to device labeling. North Carolina's management is aware of the issues with respect to the SS&D evaluation program and noted that since the last IMPEP review, the Branch prioritized other areas of their program which encompass the greatest percentage of their activities, such as licensing, inspections, and incident response. Branch and Section management offered several avenues they will consider to improve the SS&D evaluation program, such as additional specialized training for all reviewers, round-table reviews of incoming evaluations, and reaching out to other Agreement States or the NRC for technical assistance.

Because of the issues noted above, based on the criteria in MD 5.6, the team recommended that North Carolina's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory, but needs improvement.

d. MRB Decision

The MRB agreed with the team's recommendation and found North Carolina's performance with respect to this indicator to be satisfactory, but needs improvement.

4.3 Low-Level Radioactive Waste Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need for an amendment. Although North Carolina has such authority to regulate a LLRW disposal facility, the NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for LLRW disposal. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW program. There are no plans for a commercial LLRW disposal facility in North Carolina. Accordingly, the team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, North Carolina's performance was found to be satisfactory for six out of seven performance indicators reviewed and satisfactory, but needs improvement, for the non-common performance indicator, Sealed Source and Device Evaluation Program. The MRB agreed with the single recommendation made by the team regarding North Carolina's performance and agreed that the three recommendations from the 2014 IMPEP review should be closed.

Accordingly, the team recommended, and the MRB agreed, that the North Carolina Agreement State Program is adequate to protect public health and safety and compatible with the NRC's program. When weaknesses in a program result in, or could result in, less than fully satisfactory performance for one or more performance indicators, the NRC's MD 5.6 states that the MRB should consider whether Monitoring by the NRC is warranted. The team discussed whether or not Monitoring was appropriate based on the satisfactory, but needs improvement, finding for the indicator SS&D Evaluation Program. Based on North Carolina's willingness and promptness to correct the deficiencies in its SS&D Evaluation Program, the mitigating circumstances related to the deficiencies, and the low volume of evaluations completed by the staff each year, the team stated that North Carolina did not warrant Monitoring. Instead, the team recommended that a periodic meeting take place in approximately one year with the intent to conduct the next IMPEP review in four years. The MRB agreed that Monitoring was not necessary, but directed that a periodic meeting take place approximately 18 months following the 2018 IMPEP review.

The meeting should include an extended discussion on North Carolina's SS&D evaluation program. This timing would give North Carolina time to take actions to address the deficiencies noted in Section 4.2. Depending upon the progress noted at the time of the periodic meeting, the MRB may choose to direct a period of Monitoring, a

followup review, a second periodic meeting, or alter the timing of the next full IMPEP review.

Below is a recommendation, as mentioned in the report, for evaluation and implementation by North Carolina:

North Carolina should take action to: (1) improve the thoroughness, completeness, accuracy, and consistency of SS&D reviews and ensure that the reviews address health and safety concerns and product integrity; (2) improve the concurrence review process to ensure that concurrence reviewers fully assess SS&D evaluations; and (3) ensure that each SS&D evaluation is properly documented, including all licensee correspondence, deficiency letters and responses, and memos to file.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Areas of Responsibility**
Lance Rakovan, NMSS	Team Leader Technical Staffing and Training Compatibility Requirements
Monica Ford, Region I	Status of Materials Inspection Program Technical Quality of Incident and Allegation Activities
Jackie Cook, Region IV	Technical Quality of Licensing Actions
Celimar Valentin-Rodriguez, NMSS	Sealed Source and Device Evaluation Program
Jimmy Uhlemeyer, KS	Technical Quality of Inspections Inspection Accompaniments

APPENDIX B

INSPECTION ACCOMPANIMENTS

The following inspection accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1	License No.: 0021-3
License Type: *High Dose Remote Afterloader*	Priority: 2
Inspection Date: 01/22/18	Inspector: SJ

Accompaniment No.: 2	License No.: 1117-3
License Type: *Industrial Radiography (Security inspection)*	Priority: 1
Inspection Date: 01/23/18	Inspector: TC

Accompaniment No.: 3	License No.: 0668-3
License Type: *Medical Private Practice*	Priority: 5 (3 in NC)
Inspection Date: 01/24/18	Inspector: CH

Accompaniment No.: 4	License No.: 1064-2
License Type: *Portable Gauge*	Priority: 5 (3 in NC)
Inspection Date: 01/25/18	Inspector: CS